## **DSJ1&2-PR Exh 595**

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From: Zimmerman, Chris

**Sent:** Tue, 17 Nov 2015 18:28:30 -0500 (EST)

To: Mauch, Robert[RMauch@amerisourcebergen.com]

**Subject:** RE: Follow-up with DEA

Bob, we will take a look and provide you with our recommendations. Just for your information, and I would rather not share with HDMA, but Lou Milione, the person that John Gray had a conversation with from DEA, is a good friend of David May. They entered DEA together 30 years ago and worked closely together for the last 30 years at DEA until David retired. David has already had a couple of meetings with Lou. I would like to keep that information confidential.

I will pull the information together and get back to you.

Thank Bob.

Chris

From: Mauch, Robert

Sent: Tuesday, November 17, 2015 2:32 PM

To: Zimmerman, Chris

Subject: FW: Follow-up with DEA

Chris,

HDMA is resubmitting questions to the DEA and would like to update them as well as make sure that our respective compliance leaders have a chance to comment. Will you or David take a look at these and provide comments if applicable?

Bob

From: Gray, John [mailto:jgray@hdmanet.org] Sent: Tuesday, November 17, 2015 2:23 PM

To: Mauch, Robert; Dale Smith; Gray, John; Jon Giacomin; Ken Couch; Mark Walchirk; Moody, David; Scherr, Ted

**Cc:** Kelly, Patrick; Johnson, Anne **Subject:** FW: Follow-up with DEA

To: HDMA Executive Committee Members

From: John Gray

Patrick Kelly

**Subject:** Follow-up with DEA

Per last week's conversation with Louis Milione of the DEA, attached for your review are the questions that HDMA submitted to DEA in 2013. As you may recall from the email detailing the conversation with Mr. Milione (see below), we referenced the fact that HDMA had submitted questions to DEA regarding suspicious order monitoring protocols on several occasions but never got a response from the agency. Mr. Milione said he was unaware of these questions and suggested we forward them to his attention.

While it has been more than two years since the questions were submitted, many of them are still relevant. However, we want to defer to your DEA compliance teams prior to resubmitting the questions.

Action Requested: Please have your compliance personnel review the attached questions and get back us by Tuesday, November 24, with any edits or concerns you may have about resubmitting these questions to DEA. Please forward responses to Patrick Kelly at <a href="mailto:pkelly@hdmanet.org">pkelly@hdmanet.org</a>. Patrick will be compiling any edits or revisions to the questions and preparing an updated document.

On a coincidental and very positive note, based on my conversation last Thursday evening asking Mr. Milione to help expedite the Hatch/Whitehouse legislation, S. 483, on Friday we were informed that DEA has agreed not to oppose bill. They have agreed to accept a definition of "imminent danger" that Senators Hatch and Whitehouse offered (and all stakeholders agreed to) in early September.

Consensus language: "In this subsection, the phrase 'imminent danger to the public health or safety' means that, due to the failure of the registrant to maintain effective controls against diversion or otherwise comply with the obligations of a registrant under this subchapter or subchapter II of this title, there is a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration."

Hatch and Whitehouse are now working to schedule a markup in the Senate Judiciary Committee and possibly a vote on the legislation in December.

If you have any questions or need additional information, please contact me directly by email or by phone at (703) 885-0219 or Patrick Kelly at (703) 885-0233.

----- Original message -----

From: John Gray <<u>igray45887@aol.com</u>> Date: 11/13/2015 3:51 AM (GMT-05:00)

To: Scherr Ted < tscherr@dakdrug.com >, Giacomin Jon < jon.giacomin@cardinalhealth.com >, Smith Dale

<<u>dsmith@hdsmith.com</u>>, Mauch Robert <<u>rmauch@amerisourcebergen.com</u>>, David Moody <<u>DMoody@mutualdrug.com</u>>,

Walchirk Mark < Mark. Walchirk@Mckesson.com >, Couch Ken < kencouch01@yahoo.com >

Cc: Kelly Patrick < pkelly@hdmanet.org>

Subject: DEA Phone Call

## Gentlemen:

Last night I spoke with Lou Milione, Deputy Assistant Administrator, Office of Diversion, DEA. Mr. Milione replaced Joe Rannazzisi on October 1. We spoke for twenty minutes about how DEA wants to "engage" with HDMA and our members going forward. He acknowledged that the DEA is ready and willing to meet with us and to maintain an open dialogue with our industry. He described all this as a "reset" opportunity for them. He and his team, as directed by the new DEA Administrator, Chuck Rosenberg, want to meet with us to begin this effort.

His plan is to schedule an in person meeting with me and relevant HDMA staff in early January at their offices. He indicated they may expand the group to include some of our members and possibly other trade associations. He did not specify which members or which trade associations may also be invited. I think it will depend on the breadth and scope of the agenda.

Both he and Chuck Rosenberg will be part of the meeting to introduce their new team and explain DEA's plans going forward in working with us. He said "we" will draft an agenda in the next month or so. I immediately volunteered to send him a draft agenda featuring those issues that HDMA will want to discuss. I mentioned to him that we have had a number of detailed questions that were submitted to DEA several years ago concerning suspicious order matters that were never answered. He was unaware of these questions. I told him I would send him a copy of these outstanding questions along with our proposed agenda. He was very appreciative of the offer.

I asked him to try and expedite the DOJ response to the technical corrections in the Hatch/Whitehouse, S. 483. He said he was not directly involved in those corrections but insisted that DEA wants to move this legislative process along also. I told him that the Senate was anxious to move this bill and he was very positive about it.

I extended an invitation to both he and/ or Chuck Rosenberg to speak at our March Distribution Management Conference since DEA stopped attending last year. He said they would definitely participate and would determine exactly who would attend. I asked him to be sure to bring a new presentation this time since the last two years the DEA presented the exact same information and it offered no new perspectives on the critical issues. He did laugh at this and assured me they would absolutely present a new perspective and he apologized for his predecessor's actions here.

I also mentioned the Marino request for a meeting with the US AG and HDMA, NACDS and NCPA. He was generally aware of this and was not certain whether or not our upcoming January meeting might serve as that meeting.

Finally, I thanked him for reaching out. I told him it was the first conversation I had had with any DEA official since I have

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been with HDMA. He was disappointed with that fact. I told him we were anxious to reopen dialogue and that the cost of not being able to communicate was lack of clarity and misunderstandings. I concluded that by working together our members and DEA can make real progress in curbing the drug abuse and diversion problem.

Overall, he was engaging, exceedingly pleasant and seemed genuinely concerned that we had lost touch with each other. Time will tell, but it is a VERY different tone and approach than we have all seen in the past 8-10 years.

We will begin immediately assembling a draft agenda and will seek input from your companies on the draft.

Please let me know if you have any questions about this call.

John

Sent from my iPhone

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